

INDIAN PHARMACOPOEIA COMMISSION

Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad 201002

Minutes of 53rd Meeting of the Scientific Body (SB) of IPC

Date of Meeting : December 30, 2023

Chairperson : Dr. V. M. Katoch

The list of participants is appended as Enclosure-I.

Welcome and Opening of the Meeting

At the outset, Dr. Rajeev Singh Raghuvanshi welcomed the Chairperson and members of the Scientific Body for the 53rd meeting of the Scientific Body of IPC. With the permission of the Chairperson, Dr. Raghuvanshi made a presentation on the progress and key achievements made by the IPC since the last meeting of the Scientific Body.

Scientific Body took note of the key achievements of the IPC and appreciated the efforts made by IPC towards development of monographs for the next IPAddendum 2024, membership of the IPC in the Pharmacopoeial Discussion Group (PDG), increase in the number of IP Reference Standards (IPRS) and Impurity Standards, conducting Proficiency Testing (PT) Program, expansion of Pharmacovigilance and Materiovigilance Programmes of India, stakeholders' meets, publications, and revenue generation.

After reviewing the progress of the IPC, Scientific Body suggested that IPC scientists should write projects on new subject areas for obtaining extramural research grants from different agencies which will help engaging additional manpower on ad-hoc basis to work with IPC and increase the output. Also, the research findings from these projects will increase research publications to IPC's credit. Dr. Bikas Medhi offered to organize a workshop for writing research papers.

Thereafter, main agenda was presented in following sequence and decisions of the Scientific Body were recorded as below:

Item 1. Confirmation of the Minutes of 52nd Meeting of the SB held on August 12, 2023

The minutes were confirmed by the Scientific Body.

Item 2. Action Taken Report on the Minutes of 52nd Meeting of the SB held on August 12, 2023

Noted by the Scientific Body.

MAIN AGENDA

Item 3. Progress of AR&D Division

Scientific Body noted work progress of AR&D Division w.r.t. development of monographs for the IP Addendum 2024, monograph revisions and upgradations w.r.t. inclusion of tests on dissolution and related substances, development of IP on-line portal, organizing IPC Interactive Meet and stakeholder's meeting, student training, and publications. IPC's membership in the Pharmacopoeia Discussion Group (PDG) was appreciated by the Scientific Body.

While reviewing the monograph list of veterinary medicines, Scientific Body suggested omitting monograph on Diclofenac Injection as the same has been banned in India for veterinary use. Also, the issue of the use of specific columns in newly developed monographs was highlighted during the meeting to which Scientific Body suggested to further discuss this matter in the Expert Working Group (EWG).

Item 4. Progress of Biologics Section

Scientific Body noted the work progress of Biologics Division during the index period w.r.t. development and revision of human and veterinary biological monographs and general chapters, EWG meetings, PT program, and student training. Signing and renewal of MoUs between IPC and other Institutes was also noted. New monograph (i.e. Hepatitis B Immunoglobulin for Intravenous Use), revised general chapter and proposal for amendments in monograph and general chapter submitted were approved.

Scientific Body suggested that IPC should also focus on NGS for detection of adventitious agents. It was also suggested to refer to WHO Position Paper while taking decisions on removing test for abnormal toxicity from individual monographs.

Item 5. Progress of Microbiology Division

Scientific Body noted the progress made by Microbiology Division w.r.t. development and upgradation of General Chapters for the IP addendum 2024, analytical testing (including testing of cough syrups), and conducting meetings of EWG. Scientific Body appreciated for successful completion of Proficiency Testing Programme (PTP) in biological domain (i.e. test for specified microorganisms) as per NABL for ISO/IEC 17043:2010 as PT provider.

Item 6. Progress of Phytopharmaceuticals Division

Scientific Body noted development of monographs and general chapters on phytopharmaceuticals for the IP Addendum 2024. Progress made by the Division w.r.t. EWG meetings and trainings was also noted.

Item 7. Progress of Reference Standard Division

Scientific Body noted the work done by the Division for the development of new IPRS and Impurity standards, lot changes of the reference standards, analysis of drugs (including cough syrups), and revenue generation. It was emphasized by the Scientific Body that IPC should make efforts to further increase the number of Impurity standards in the inventory so as to cover a greater number of IP monographs. The issues of stability of IPRS and impurities and their expiry were also discussed. It was appraised to the Scientific Body that IPC will give a statement regarding the validity of standards on their certificates to address the concerns of the stakeholders.

Item 8. Progress of Quality Assurance (QA) Division

Scientific Body noted progress of the Division in the area of maintaining certification and accreditation activities, conducting proficiency testing (PT) programmes, internal quality checks, and trainings provided to students.

Item 9. Progress of Pharmacovigilance Programme of India (PvPI)

Scientific Body noted the progress of PvPI for reporting of ADRs, expansion of AMCs across India, issuing drug safety alerts, and stakeholders' meetings. Scientific Body appreciated the PvPI for reaching fourth position globally in terms of contribution of ICSRs in the global database.

Scientific Body suggested that in order to further expand PvPI, efforts should be made to establish AMCs in all States and UTs with special focus on border areas. PvPI should also have collaborations with other National Institutes like PGI, AIIMS, NIPERs, and other Institutes/Universities who are working on pharmacovigilance and should come up with a draft program for outreach of pharmacovigilance among public. PvPI should also establish linkages with neighboring countries by conducting training programs under the ITEC scheme of the Ministry of External Affairs.

Item 10. Progress of Materiovigilance Programme of India (MvPI)

Progress of MvPI activities was noted by the Scientific Body for integration with public health programme, reporting of MDAEs, expansion of MDMCs across India, and training programmes conducted.

Item 11. Progress of Publication Division

Noted by the Scientific Body.

Item 12. Revenue Generation

Noted and appreciated by the Scientific Body.

Item 13. Any Other Item with Permission of the Chairperson

Following additional agenda points were also discussed during the meeting:

I. To Charge Fee from Students Undergoing Training at IPC

It was proposed by the IPC to charge fee from undergraduate, postgraduate, and other students who undergo their training and dissertation at IPC. Scientific Body suggested for developing a written SOP for training program at IPC and the same should include criteria for induction of students, number of trainees etc. Calendar for providing training should also be prepared and made publicly available. Following training fee was approved by the Scientific Body:

Training Period	Training Fee
1 month	Rs. 2000/-
>1-3 months	Rs. 5000/-
>3-6 months	Rs. 10000/-

II. Affiliation of the IPC with AcSIR for Ph.D. Program

IPC proposed to start Ph.D. program in affiliation with the CSIR's Academy of Scientific and Innovative Research (AcSIR). Scientific Body welcomed the proposal as the same would strengthen scientific ecosystem within the IPC along with potential of societal benefits and creating a pool of young researchers to better contribute to the overall regulatory system of India. Scientific Body approved the proposal with following suggestions:

- Ph.D. program should be focussed on research in regulatory sciences, and drug quality and safety. Problem statements should be in line with the mandates of IPC,
- Number of Ph.D. students to be enrolled should be limited so that this program does not impact the current work of the Institute,
- Written procedure should be established with specific mention of the selection criteria for the enrolment of students (e.g. those who have qualified JRF exams and having their own fellowships to support research and/or internal candidates),
- If needed, a separate 'Research Wing' may be created within the IPC to coordinate the activities of the Ph.D. program.

The meeting ended with a vote of thanks to the Chairperson and Members of the Scientific Body of IPC by the Member Secretary.

List of Scientific Body Members Participated

1. Dr. V. M. Katoch, Former DG-ICMR cum Secretary-Department of Health Research and Chairperson, Scientific Body-IPC (connected through VC)
2. Dr. D. Srinivasa Reddy, Director, IICT-Hyderabad (connected through VC)
3. Dr. A. K. Singh, Former Director General (LS), DRDO-New Delhi
4. Mr. A. K. Pradhan, JDC(I), CDSCO-New Delhi (connected through VC)
5. Dr. Bikash Medhi, Deptt. of Pharmacology, PGIMER-Chandigarh
6. Prof. Sanjeev Sinha, Deptt. of Medicine, AIIMS-Delhi (connected through VC)
7. Dr. Arvind K. Bansal, Deptt. of Pharmaceutics, NIPER-Mohali (connected through VC)
8. Dr. N. Bhaskar, Advisor (Science and Standards), FSSAI-New Delhi (connected through VC)
9. Sh. Zoher Sihorwala, Head-Global Regulatory Affairs, Wockhardt-Aurangabad
10. Dr. Sunil Gairola, Executive Director, Serum Institute-Pune (connected through VC)
11. Dr. C. Hariharan, Director, RDTL-Guwahati (connected through VC)
12. Sh. D. R. Gahane, Joint Commissioner, Food and Drugs Administration-Mumbai (connected through VC)
13. Dr. Ravi P. Singh, Provost. Adani University-Ahmedabad (connected through VC)
14. Dr. Anil Kumar Tyagi, Chief Scientific Officer, Mankind Pharma-Gurugram (connected through VC)
15. Dr. D. J. Kalita, Head-Technical and Regulatory, Zenex Animal Health India Pvt. Ltd.-Ahmedabad (connected through VC)
16. Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific Director-IPC and Member Secretary

Leave of Absence

1. Prof. Sanjay Singh, Vice Chancellor, BBAU-Lucknow
2. Dr. Hemant Koshia, Commissioner-Food and Drug Control Administration-Ahmedabad
3. Dr. Inder Pal Singh, Deptt. of Natural Products, NIPER-Mohali
4. Dr. Amulya K. Panda, Former Director, NII-Delhi
5. Dr. Naresh Bhatnagar, Deptt. of Mechanical Engg., IIT-Delhi